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Commissioner for Patents  
Washington, DC 20231

Re: *U.S. Patent Application No. 09/923,304 entitled "DETECTION AND DIAGNOSIS OF SMOKING RELATED CANCERS" by Ruth Katz and Feng Jiang*  
*Our Reference: UTSC:658US*  
*Client Reference: MDA00-038*

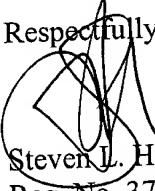
Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references (C1-C65).

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10108230/SLH.

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Respectfully submitted,

  
Steven L. Highlander  
Reg. No. 37,642

SLH/cmb  
Encl.: as noted

25185414.1

**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Ruth Katz  
Feng Jiang

Serial No.: 09/923,304

Filed: August 6, 2001

For: DETECTION AND DIAGNOSIS OF  
SMOKING RELATED CANCERS



Group Art Unit: 1634

Examiner: Goldberg, Jeanine Anne

Atty. Dkt. No.: UTSC:658US

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Date	Steven A. Highlander

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

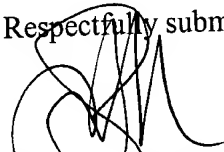
In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10108230/SLH.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
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UTSC:658USSerial No.  
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List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

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Applicant  
Ruth Katz  
Feng JiangFiling Date:  
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## U.S. Patent Documents

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## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Alberola <i>et al.</i> , "Prognostic significance of flow cytometry and EGFR in resectable non-small cell lung cancer (NSCLC): results of a prospective study," <i>Proc. Annu. Mt. Am. Soc. Clin. Oncol.</i> , 14: 359, Abstract A1094, 1995.
	C2	Auerbach <i>et al.</i> , "Changes in bronchial epithelium in relation to cigarette smoking and in relation to lung cancer," <i>N. Engl. J. Med.</i> , 265: 253-267, 1961.
	C3	Ayabe <i>et al.</i> , "DNA stemline heterogeneity of non-small cell lung carcinomas and differences in DNA polidy between carcinomas and metastatic nodes," <i>Lung Cancer</i> , 11(3-4): 201-208, 1994.
	C4	Barinaga, "An intriguing new lead on Huntington's Disease," <i>Science</i> , 271: 1233-1234, 1996.
	C5	Bepler <i>et al.</i> , "Association of chromosome 11 locus D11S12 with histology, stage, and metastases lung cancer," <i>Cancer Detection and Prevention</i> , 22(1):14-29, 1998.
	C6	Bockmuhl <i>et al.</i> , "Deletion of chromosome 10q—a marker for metastasis of head-neck carcinomas?" <i>Laryngorhinootologie</i> , 79(2):81-85, 2000, article in German, English abstract included.
	C7	Brugal <i>et al.</i> , "Image analysis of microscopic preparations," <i>Method. Achiev. Exp. Pathol.</i> , 11: 1-33, 1984.
	C8	Carney <i>et al.</i> , "Influence of histologic subtype of small cell carcinoma of the lung on clinical presentation, response to therapy and survival," <i>JNCI</i> , 65:1225-1230, 1980.
	C9	Carriaga <i>et al.</i> , "The histologic grading of cancer," <i>Cancer</i> , 75:406-421, 1995.

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1634Other Art  
See Page 1

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	C10	Cheon <i>et al.</i> , "Flow cytometric analysis of DNA ploidy in primary non-small cell carcinoma of the lung in Korea," <i>Yonsei Med. J.</i> , 34(4): 365-370, 1993.
	C11	Czerniak <i>et al.</i> , "Genetic model of human urinary bladder carcinogenesis," <i>Genes, Chromosomes, and Cancer</i> , 27:392-402, 2000.
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	C13	Dalquen <i>et al.</i> , "DNA aneuploidy, s-phase fraction, nuclear p53 positivity, and survival in non-small-cell lung carcinoma," <i>Virchows Archiv.</i> , 431(3): 173-179, 1997.
	C14	Daly <i>et al.</i> , "A homozygous deletion on chromosomes 3 in small cell lung cancer cell line correlates with a region of tumor suppressor activity," <i>Oncogene</i> , 8(7):1721-1729, 1993.
	C15	Dong <i>et al.</i> , "KAI1, a metastasis suppressor gene for prostate cancer on human chromosome 11p11.2," <i>Science</i> , 268:884-886, 1995.
	C16	Feder <i>et al.</i> , "Clinical relevance of chromosome abnormalities in non-small cell lung cancer," <i>Cancer Genet. Cytogenet.</i> , 102: 25-31, 1998.
	C17	Feinstein <i>et al.</i> , "Observer variability in the histopathologic diagnosis of lung cancer," <i>Am Rev Respir Dis</i> , 101:671-684, 1970.
	C18	Feinstein <i>et al.</i> , "The diverse effects of histopathology on manifestations and outcome of lung cancer," <i>Chest</i> , 66(3):225-229, 1974.
	C19	Field <i>et al.</i> , "Genetic alterations in bronchial lavage as a potential marker for individuals with a high risk of developing lung cancer," <i>Can Res.</i> , 59:2690-2695, 1999.
	C20	Fontanini <i>et al.</i> , "The expression of proliferating cell nuclear antigen in paraffin sections of peripheral, Node-negative non-small cell lung cancer," <i>Cancer</i> , 70(6): 1520-1527, 1992.
	C21	Hirano <i>et al.</i> , "Genesis of squamous cell lung carcinoma. Sequential changes of proliferation, DNA ploidy, and p53 expression," <i>American J. Path.</i> , 144(2): 296-302, 1994.
	C22	Hirsch <i>et al.</i> , "Intracranial metastases in small cell carcinoma of the lung," <i>Cancer</i> , 51:529-533, 1983.

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Ruth Katz

Feng Jiang

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Exam. Init.	Ref. Des.	Citation
	C23	Hirsch <i>et al.</i> , "The prognostic significance of histopathologic subtyping of small cell carcinoma of the lung according to the classification of the world health organization," <i>Cancer</i> , 52:2144-2150, 1983.
	C24	Hung <i>et al.</i> , "Allele-specific chromosome 3p deletions occur at an early stage in the pathogenesis of lung carcinoma," <i>JAMA</i> , 273(7):558-563, 1995.
	C25	Ichinose <i>et al.</i> , "Postoperative adjuvant chemotherapy in non-small cell lung cancer: prognostic value of DNA ploidy and post-recurrent survival," <i>J. Surgical Oncology</i> , 46(1): 15-20, 1991.
	C26	Ihde, "Non-small cell lung cancer. Biology, diagnosis and staging," <i>Curr. Prob. Cancer</i> , 15:63-104 1991.
	C27	Kim <i>et al.</i> , "DNA ploidy and proliferative activity in bcl-2 expressed non-small cell lung cancer," <i>Korean J. Intern. Med.</i> , 11(2):101-107, 1996.
	C28	Licciardello <i>et al.</i> , "Multiple primary cancer in patients with cancer of the head and neck: second cancer in the head and neck, esophagus and lung," <i>Int. J. Radiat. Oncol. Bio. Phys.</i> , 17: 467-476, 1989.
	C29	Liewald <i>et al.</i> , "Flow cytometric analysis of non-small-cell bronchial carcinoma and its prognostic significance," <i>Chirurg</i> , 63(3): 205-210, 1992, Article in German, English abstract included.
	C30	Lifton, "Molecular genetics of human blood pressure variation," <i>Science</i> , 272: 676-680, 1996.
	C31	Macchiarini <i>et al.</i> , "Risk of cancer recurrence in completely resected T1N0M0 non-small cell lung cancer (NSCLC)," <i>Proc Annu Mt. Am. Soc. Clin. Oncol.</i> 11:297, abstract # 995, 1992.
	C32	Miki <i>et al.</i> , "A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1," <i>Science</i> , 266: 66-71, 1994.
	C33	Mitsudomi <i>et al.</i> , "Loss of heterozygosity at 3p in non-small cell lung cancer and its prognostic implication," <i>Clin. Cancer Res.</i> , 2(7): 1185-1189, 1996.
	C34	Miura <i>et al.</i> , "Chromosome alterations in 21 non-small cell lung carcinomas," <i>Genes Chromosomes Cancer</i> , 2(4):328-338, 1990.
	C35	Miyamoto <i>et al.</i> , "Prognostic value of nuclear DNA content and expression of the RAS oncogene product in lung cancer," <i>Cancer Research</i> , 51: 6346-6350, 1991.
	C36	Morahan <i>et al.</i> , "Markers on distal chromosome 2q linked to insulin-dependent diabetes mellitus," <i>Science</i> , 272: 1811-1813, 1996.

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	C37	Morkve <i>et al.</i> , "Prognostic significance of p53 protein expression and DNA ploidy in surgically treated non-small cell lung carcinomas," <i>Anticancer Research</i> , 13(3): 571-578, 1993.
	C38	Muguerza <i>et al.</i> , "Prognostic value of flow cytometric DNA analysis in small-cell lung cancer: rationale of sequential processing of frozen and paraffin-embedded tissue," <i>World J. Surg.</i> 21(3): 323-329, 1997.
	C39	Naruke <i>et al.</i> , "Prognosis and survival in resected lung carcinoma based on the new international staging system," <i>J. Thorac. Cardiovas. Surg.</i> , 96:440-447, 1988.
	C40	Pantel <i>et al.</i> , "Expression of Lewis Y blood group precursor antigens on non-small cell lung carcinomas is associated with an unfavorable prognosis," <i>Proc. Annu Mt. Am. Soc. Clin. Oncol.</i> , 12:290, abstract # 941, 1993.
	C41	Papadimitrakopoulou <i>et al.</i> , "Molecular and cellular biomarkers for field cancerization and multistep process in head and neck tumorigenesis," <i>Cancer and Metastasis Reviews</i> , 15: 53-76, 1996.
	C42	Pence <i>et al.</i> , "Prognostic significance of the proliferation index in surgically resected non-small-cell lung cancer," <i>Archives of Surgery</i> , 128(12): 1382-1390, 1993.
	C43	Rice <i>et al.</i> , "Prognostic significance of flow cytometry in non-small-cell lung cancer," <i>J. Thoracic Cardio. Surgery</i> , 106(2): 201-217, 1993.
	C44	Sahin <i>et al.</i> , "Flow cytometric analysis of the DNA content of non-small-cell lung cancer. Ploidy as a significant prognostic indicator in squamous cell carcinoma of the lung," <i>Cancer</i> , 65(3): 530-537, 1990.
	C45	Shiseki <i>et al.</i> , "Comparative allelotype of early and advanced stage non-small cell lung carcinomas," <i>Genes Chromosomes Cancer</i> , 17(2): 71-77, 1996.
	C46	Shriver <i>et al.</i> , "Trinucleotide repeat length variation in the human ribosomal protein L14 gene (RPL14): localization to 3p21.3 and loss of heterozygosity in lung and oral cancers," <i>Mutat. Res.</i> 406(1): 9-23, 1998.
	C47	Sidransky <i>et al.</i> , "Identification of p53 gene mutations in bladder cancers and urine samples," <i>Science</i> , 252: 706-709, 1991.
	C48	Siebert <i>et al.</i> , "Detection of deletions in the short arm of chromosome 3 in uncultured renal cell carcinomas by interphase cytogenetics," <i>J. Urol.</i> , 160(2):534-539, 1998.

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C49	Slamon <i>et al.</i> , "Studies of the HER-2/new proto-oncogene in human breast and ovarian cancer," <i>Science</i> , 244: 707-712, 1989.
	C50	Taparowsky <i>et al.</i> , "Activation of the T24 bladder carcinoma transforming gene is linked to a single amino acid change," <i>Nature</i> , 300: 762-765, 1982.
	C51	Thiberville <i>et al.</i> , "Evidence of cumulative gene losses with progression of premalignant epithelial lesions to carcinoma of the bronchus," <i>Cancer Research</i> , 55: 5133-5139, 1995.
	C52	Thiberville <i>et al.</i> , "Frequency and prognostic evaluation of 3p21-22 allelic losses in non- small-cell lung cancer," <i>Int. J. Cancer</i> , 64:371-377, 1995.
	C53	Travis <i>et al.</i> , "Lung Cancer," <i>Cancer</i> , 75:191-202, 1995.
	C54	Valdivieso <i>et al.</i> , "Clinical and molecular markers of prognosis in non-small cell lung cancer (NSCLC)," <i>Proc. Annu. Mt. Am. Soc. Clin. Oncol.</i> , 13:337, abstract # 1121, 1994.
	C55	Vollmer <i>et al.</i> , "Subclassification of small cell cancer of the lung," The Southeastern Study Group Experience, <i>Hum Pathol</i> , 16:247-252, 1985.
	C56	Volm <i>et al.</i> , "Prognostic significance of DNA ploidy and distribution of cell cycle phases in non-small cell bronchial cancer," <i>Versicherungsmedizin</i> , 41(1): 2-5, 1989, Article in German, English abstract included.
	C57	Voravud, <i>et al.</i> , "Increased polysomies of chromosomes 7 and 17 during head and neck multistage tumorigenesis," <i>Cancer Research</i> , 53: 2874-2883, 1993.
	C58	Whang-Peng <i>et al.</i> , "A nonrandom chromosomal abnormality, del 3p(14-23), in human small cell lung cancer (SCLC)," <i>Cancer Genet. Cytogenet.</i> , 6(2):119-134, 1982.
	C59	Wiest <i>et al.</i> , "Genetic markers for early detection of lung cancer and outcome measures for response to chemoprevention," <i>J. Cell Biochem. Suppl.</i> , 28/29:64-73, 1997.
	C60	Wistuba <i>et al.</i> , "High resolution chromosome 3p allelotyping of human lung cancer and preneoplastic/preinvasive bronchial epithelium reveals multiple, discontinuous sites of 3p allele loss and three regions of frequent breakpoints," <i>Cancer Res.</i> , 60(7): 1949-1960, 2000.
	C61	Wu <i>et al.</i> , "Benzo[a]pyrene diol epoxide-induced 3p21.3 aberrations and genetic predisposition to lung cancer," <i>Cancer Res.</i> , 58(8): 1605-1608, 1998.
	C62	Wu <i>et al.</i> , "Chromosome 5 aberrations and genetic predisposition to lung cancer," <i>Int J. Cancer</i> , 79(5):490-493, 1998.

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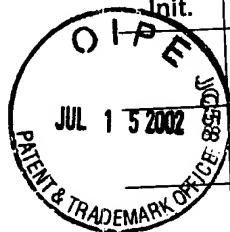
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Exam. Init.	Ref. Des.	Citation
	C63	Yamaoka <i>et al.</i> , "The prognostic significance of nuclear DNA content in non-small-cell lung carcinoma," <i>J. Japan Surgical Soc.</i> , 91(10): 1608-1616, 1990, Article in Japanese, English abstract included.
	C64	Yanagisawa <i>et al.</i> , "Molecular analysis of the FHIT gene at 3p14.2 in lung cancer cell lines," <i>Cancer Research</i> , 56: 5579-5582, 1996.
	C65	Zou <i>et al.</i> , "Higher potency of N-(4-Hydroxyphenyl)retinamide that all-trans-retinoic acid in induction of apoptosis in non-small cell lung cancer cell lines," <i>Clinical Cancer Research</i> 4: 1345-1355, 1998.

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